

P23 Laboratories Self-Collection COVID-19 PCR Testing
Standard Operating Procedure

Please note, this guidance is specific to the P23 Laboratories Self-Collection COVID-19 PCR test. If you are using testing material from any other manufacturer, please refer to the guidance for the use of that product.

August 4, 2020 Revision:

- Updates procedure for ordering shipping labels

Amendments: MOU

Purpose

This Standard Operating Procedure (SOP) will guide you in the process of requesting and utilizing the **P23 Laboratories** Self-Collection PCR Test kits that have been provided to you by the State of Tennessee.

Responsibilities

It is the responsibility of the receiving agency to properly store the test kits that have been provided. These kits do not require refrigeration but should be protected from extreme temperatures. These kits are to be used for the self-collection of nasal specimens or saliva samples for COVID-19 PCR testing. Saliva testing may only be used for individuals ages 2 years and older who can complete the procedure without assistance. There is no age restriction for the use of nasal swabs. Nasal swabs may be used for nasopharyngeal, mid-turbinate, or nasal collection. It is the responsibility of the receiving agency to ensure that registration, collection, and shipping processes and procedures are followed according to the guidance laid out in this document and the instructions provided by P23 Laboratories.

Procedures

Complete the Memorandum of Understanding (MOU)

- 1) Your organization must complete and return the attached Memorandum of Understanding, in which the organization agrees to abide by the policies and procedures, as described
- 2) Return the signed MOU to COVID19.testing@tn.gov

Request Testing Supplies

- 1) Qualifying organizations may request test kits by completing the survey found here: <https://arcg.is/1GPiOa>. If the survey will not load, use an alternate internet browser (internet explorer does not support this application)
- 2) Enter the facility type and county location of the facility
- 3) Choose from the dropdown list of qualifying entities. If your organization is not listed, email COVID19.testing@tn.gov to request approval.
- 4) Provide point of contact name, phone number, and email. The shipping address is pre-populated and should reflect the address to which the kits should be shipped. If the address needs to be changed, email COVID19.testing@tn.gov

- 5) Select "P23 Nasal Self-Collection Test Kit" or "P23 Saliva Self-Collection Test Kit", the quantity needed (nasal kits come in boxes of 50, saliva kits come in boxes of 200), the intended use of the kits (student health, employee testing, testing event, etc)
 - 6) Forecast the number of tests you anticipate will be used in the next 30 days
 - 7) Provide the number of nasal swab kits and saliva test kits currently in stock
 - 8) Provide any additional information you feel we should have in order to complete this request (e.g., if you have 200 kits on hand but have a testing event planned for 300 people, explain that you need an additional 100 kits to meet that capacity)
 - 9) Click submit
 - 10) The email provided will receive a confirmation of the placement of the request
- Note: Requests placed prior to 5pm CST Wednesday will be shipped on Thursday. Expect to receive kits within five business days. Requests placed after 5pm CST Wednesday will ship the FOLLOWING Thursday. If test kits are needed urgently, email COVID19.testing@tn.gov for assistance

Receiving Testing Supplies

- 1) Test kits will be shipped to the address provided in the online request form
- 2) Test kits must be protected from extreme temperatures
- 3) **Respond to the verification email received after the online Survey123 request for kits and verify the quantity received. Failure to verify receipt may result in delay of future shipments**
- 4) **Your facility will receive a unique User ID and password for your P23 online dashboard. This information will be sent to the email address provided when supplies were requested and should only be shared with those who should have access to ALL patient lab results**

Testing:

You should receive test kits (nasal, saliva, or both, as requested), biohazard bags, UN3773 stickers for the shipping container, and shipping container(s). It is not necessary to use a special shipping container so long as a UN3773 sticker is affixed to the container and the specimen are packed correctly (see "Ship Specimens to P23 Labs" below)

Facilities are encouraged to identify the FedEx drop boxes near their location and determine the time of the last pick-up to ensure tests that are collected are shipped out the same day, if possible.

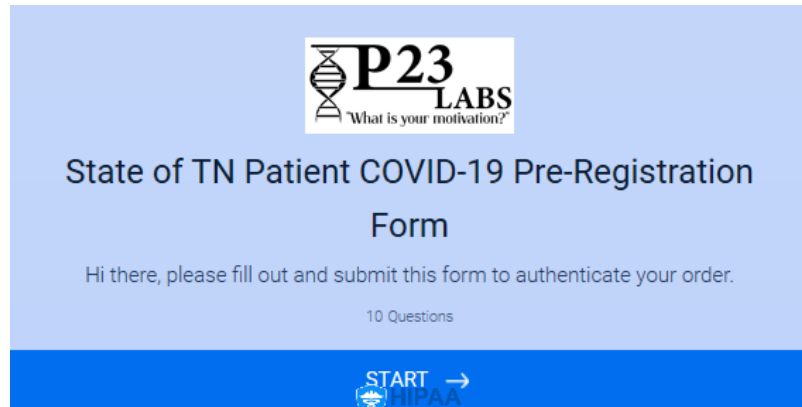
Alternately, facilities may wish to arrange for regular FedEx pickup from their location.

- 1) Identify patient for testing (e.g., patient experiencing symptoms of COVID-19, employee required to have regular testing, voluntary testing at a vulnerable population testing event, cluster investigation, etc)

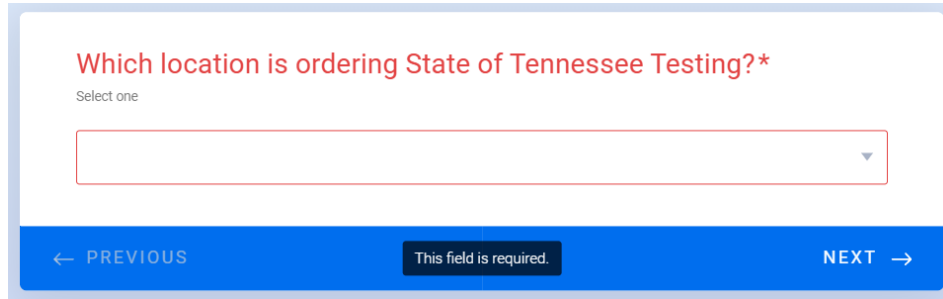
- 2) There are two options when ordering a lab for a patient:

To quickly register a patient and place an order:

- a. Visit <https://p23labs.com/tn> and click “START” from the box below:

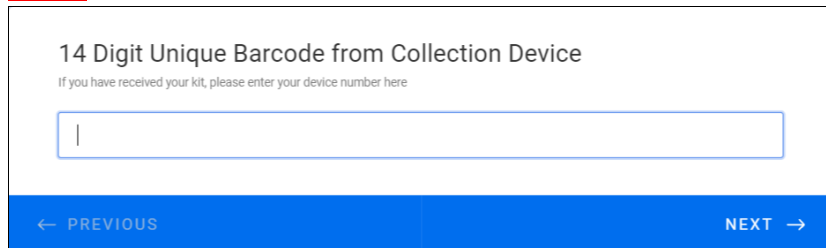


- b. Enter the patient’s first and last name and date of birth
c. Select your ordering location (facility) from the dropdown menu:



If your facility is not listed, choose “Other”. Once the order is complete, email COVID19.testing@tn.gov to request that your facility be listed in the dropdown

- d. **Enter the patient’s specimen collection kit’s unique ID number to link the patient to the kit**



- e. Enter the patient’s email address if you would like for them to receive an emailed report of their results
f. Ask the patient to consent to testing by typing their name into the box on the screen:

Consent for Testing*

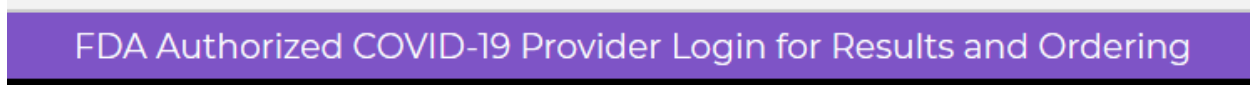
I, the undersigned, confirm and agree to the following statements regarding my laboratory service order for COVID-19 PCR testing today by my provider, deemed medically necessary, with P23 Labs. Consent to Testing: The specimen that accompanies this form is mine. I have not adulterated the specimen in any way. By typing my name below, I give my electronic signature for consent.

← PREVIOUS This field is required. NEXT →

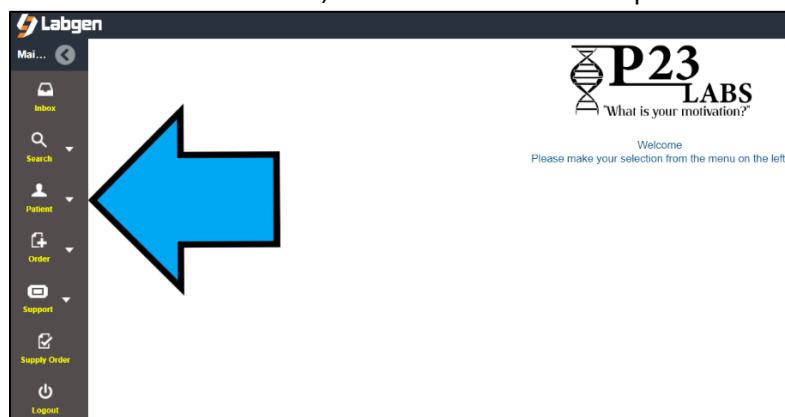
- g. Enter the email of the person completing the order
- h. Click submit
- i. The requisition will be sent to the email address that was entered by the person completing the order. Print the requisition and put one copy into the pocket of a lab sample biohazard bag. Print additional copies for your facility's records, as needed

Those provided the facility's User ID and password may also register a patient and order by logging on to the system. This provides full access to all patients and results for tests ordered by the facility. It is recommended that this access be limited to essential clinical staff for whom this access is necessary:

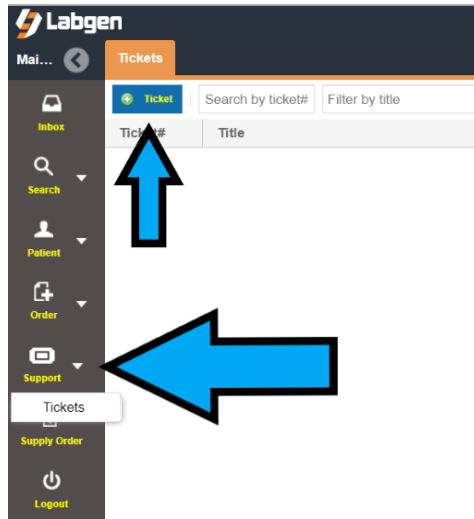
- a. Visit <https://p23labs.com/tn> and click on the purple bar at the top of the page



- b. Use your facility's P23 Labs User ID and Password to access your facility's dashboard
- c. From the menu on the left, click "Patient" and enter patient information



- i. "Chart Number" and "Room" are optional.
- ii. "Phone Number" is required. If the patient does not have a phone number, enter the facility's phone number.
- iii. Enter the patient's email if you would like the patient to receive an emailed copy of their results.
- iv. Choose your facility from the dropdown in "Patient Client". If the facility name listed is incorrect, click "Support" and "Ticket" from the menu and click "+Ticket" to request a change. (You can still proceed with the patient registration and order)



- v. Click "Save"
- d. Primary Insurance
 - i. Neither the patient nor the facility will be billed for the processing of this test; however, the registration system requires insurance information
 - ii. In the upper left corner check the box next to "Same as Patient" to auto fill the patient information
 - iii. "Selected Insurance": from the drop down, select "Bill Client". The "Client" is the State of Tennessee
 - iv. "Plan #" will automatically populate as "3". Leave that alone.
 - v. The remainder of the insurance fields should be left blank.
 - vi. Click "Save"
- e. Now the patient is fully registered and any time you order a test on this patient you will simply search for their record
- f. Facilities with large numbers of long-term residents may elect to have P23 Laboratories upload a patient roster to expedite test ordering. Email COVID19.testing@tn.gov for details
- g. Order the lab
 - i. Select "ORDER" and "Add Order" from the menu on the left and enter all or part of the patient's name. Click on the refresh icon at the right side of the search bar.



ii.

Results	Last Name	First Name	Lab ID	Chart ID	
Name	PatID	Sex	DOB	Client	
TEST, M	R0000000000	F	01/01/1990	STATE OF TENNESSEE	
TEST, M	R0000000005	F	10/05/1998	STATE OF TENNESSEE	
TEST, MICHELLE	R0000000532	F	10/18/1998	MEMPHIS MENTAL HEALTH INS	

- ii. Select the patient. Their information will auto population to the order screen.
- iii. Select "Ord. Phy" from the drop down. This is a P23 physician which relieves you of the need to provide an ordering physician for the order.
- iv. **Enter the collection kit's unique ID number in the "Cons. Phy." line**
- v. Change the order and collection dates and times, if needed.
- vi. At "Please select or type new source" choose "saliva" or "nasalpharyngeal" or type "nasal"
- vii. On the orange "test ordered" line enter "19" for the "Code", which denotes SARS-CoV2 COVID testing. Click the "+" to the right of the "Code" field to add the test, or press "Enter". The lab will then be listed below
- viii. Select "Submit" on the lower right of the screen

- ix. On the pop-up screen, enter the initials of the individual entering the order

- x. Print the ticket that pops up and put one copy into the pocket of a lab sample biohazard bag. Print additional copies for your facility's records, as needed

3) Ask the patient to collect the specimen according to the P23 Labs instructions below:



IMPORTANT: Follow all directions carefully to ensure an adequate specimen is collected for testing.

Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your saliva specimen. Do not remove the plastic film on the tube's funnel.

You can find additional guidance at:

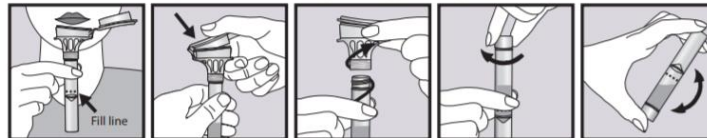
Collection steps: <https://www.dnagenotek.com/US/support/collection-instructions/omnigene-oral/om-505.html>

Collection video: <https://www.youtube.com/watch?v=l0bkXhjPVIU>

Step 1. Specimen collection

1. **IMPORTANT:** Wash your hands **thoroughly for 20 seconds** then dry your hands **before** starting the collection.
2. Open your P23 At-Home Covid-19 Test Collection Kit and place all of the contents on a clean, dry surface.
3. Remove the saliva collection device from its packaging and collect your specimen.

Read complete instructions prior to providing a saliva specimen.



1 Spit until the amount of saliva (not bubbles) reaches the fill line.

2 Close lid tightly by pushing down hard on the funnel lid until you hear a loud click.

3 Unscrew the funnel from the tube.

4 Use small cap to close tube tightly.

5 Shake the capped tube for 5 seconds.

Swab Instructions

Self-swab nasal specimen collection

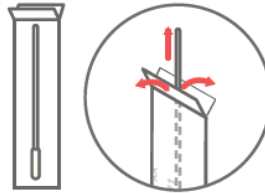
We know you aren't feeling well. Thank you for your participation. With your help, we want to understand whether people can test themselves for COVID-19 without assistance from a clinician.

These kinds of tests could one day become available for at-home swabbing for COVID-19 and other diseases like it. We appreciate your time and attention to the instructions below.

1 Open nasal swab

Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart (like you would to open a band-aid).

Be careful to only touch the handle, not the tip.



2 Swab nose

Gently insert the **entire** soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle around your nostril **4 times**.

Next, gently insert **the same swab** into the other nostril and rub it around the same way.

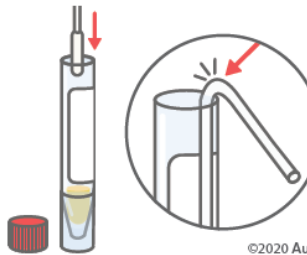


3 Put swab in tube

Lower the swab, tip first, into the provided tube.

Once the tip is at the bottom, break the swab handle at the top of the tube by bending back and forth.

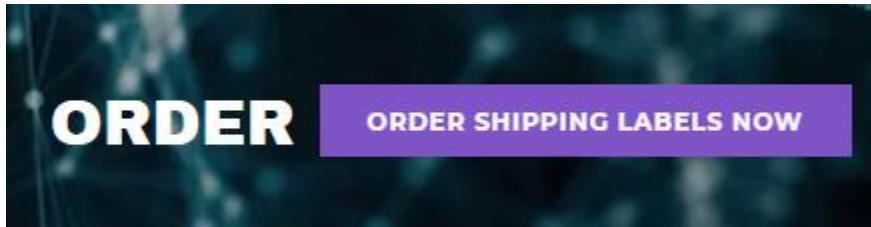
Screw the red cap on tightly.



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Ship Specimen(s) to P23 Labs:

- 1) From the www.P23labs.com/tn home page, click on



- 2) Complete the jot form and click "submit". A prepaid shipping label will be sent to the email provided in the form within 15 minutes
- 3) Ensure the screw top is secure on the specimen tube

- 4) Write the patient's name on the specimen tube
- 5) Place the specimen tube in a lab specimen biohazard bag and place the printed lab order in the front pocket
- 6) Place the bag(s) in the shipping container. You may pack as many specimens in the container as will fit. FedEx directions for packaging of biohazardous materials may be found here: https://www.fedex.com/content/dam/fedex/us-united-states/services/UN3373_fxcom.pdf
- 7) Tape up the shipping container and affix the pre-paid mailing label from P23 labs. If the shipping container is not marked UN3373, affix a UN3373 label to the package (stickers should be with your supplies).

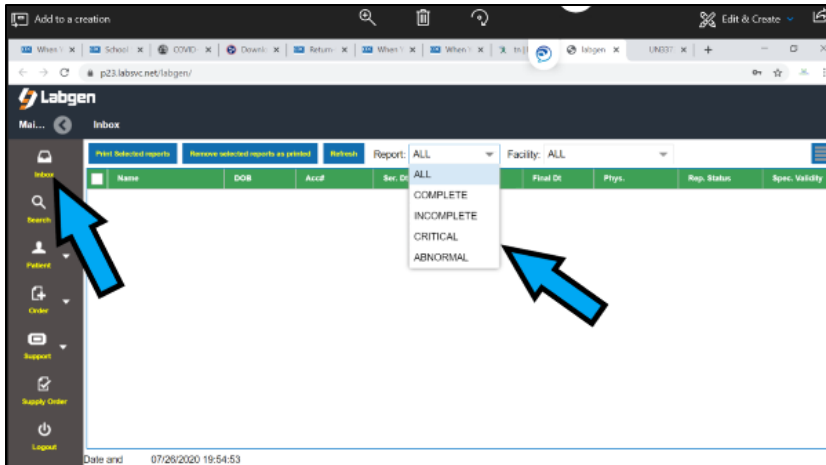
FedEx UN 3373 Pak




- 8) Ship the container via FedEx. Specimens received by 10am will be processed within 24-48h. Specimens are stable for up to seven days but should be shipped as soon as possible to ensure timely results.

Results Notification

- 1) Designated facility representative visits <https://p23labs.com/tn>, clicks on the purple bar at the top of the page, and enters the facility's User ID and password
- 2) Click on "Inbox" at the top of the menu at the left of the screen
- 3) Select the reports to view from the "Report" drop down
 - a. Complete = All completed results
 - b. Incomplete = Specimens that have been received at the lab but not yet processed
 - c. Critical = Specimens that were not processed due to being insufficient or unidentified
 - d. Abnormal = Positive results



- 4) If you have access to multiple facilities, you may filter results by facility by choosing from the “Facility” drop down
- 5) Results may also be sorted by client, report date, or collection date by clicking on the  in the upper right corner of the screen
- 6) Reports may be selected for printing individually or in batches. Click “Remove Selected Reports as Printed” to remove reports from the inbox. This will NOT permanently delete the reports. They can still be found by clicking “Search” on the menu to the left of the screen and selecting “Search Reports”
- 7) Your facility is responsible for informing patients of their results
- 8) Tennessee Department of Health receives all test results via electronic laboratory reporting (ELR) and will also attempt to contact patients who have positive test results

Billing and Payment

1. P23 Labs test kits and processing are provided at no charge by the state of Tennessee and funded by federal COVID-19 relief funding
2. Facilities are not to bill students for the cost of these tests
3. Facilities will not receive an invoice from P23 labs; the State is billed directly

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COVID-19 Testing Supplies

Memorandum of Understanding (MOU)

INSTRUCTIONS

Complete this form in its entirety and return via email at COVID19.Testing@tn.gov.
If an organization has multiple locations that are to be supplied with COVID-19 testing supplies covered by this MOU, please list the facility name, address, and primary point of contact for each location on the additional page provided.
All fields are required.

ORGANIZATION

Name of Organization, Facility, or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

☐ Check here if multiple locations from one organization are to be supplied with COVID-19 testing supplies covered by this MOU. If so, please list the facility name, address, and primary point of contact for each location on the additional page provided.

_____ Number of associated locations that are to be supplied with COVID-19 testing supplies covered by this MOU.

MEDICAL DIRECTOR

Medical Director (or equivalent) of organization, facility, or practice must have an active and unencumbered TN medical license. Write N/A if this organization does not have a medical director)

Name

Credentials

Title

TN Medical License Number

National Provider Identifier (NPI)

E-mail

POINT OF CONTACT (POC)

Point of Contact (POC) is the person completing this MOU on behalf of the organization, facility, or practice.

Name

Credentials

Title

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Phone

Fax

E-mail

AGREEMENT OF UNDERSTANDING

The State of Tennessee, through federal COVID-19 relief funding, has procured COVID-19 testing supplies to provide to certain Tennessee agencies for the purpose of performing testing on symptomatic individuals and for limited surveillance testing. In accepting the statements below, this organization (and associated facilities) agrees to abide by the following guidelines in exchange for being provided these testing supplies.

Please indicate your agreement to each of the conditions by checking "Accept" beside each statement.

The requesting organization and associated facilities agrees to:

- ☐ Accept 1. Provide COVID-19 testing to individuals who report symptoms consistent with COVID-19, who have exposure to someone who has been diagnosed with COVID-19, or who are tested as part of the organization's COVID-19 surveillance testing strategy.
- ☐ Accept 2. Store and handle the testing supplies in accordance with the package insert provided with the testing supplies.
- ☐ Accept 3. Report all test results to the Tennessee Department of Health (TDH) within 24 hours of receiving notification of results (unless a commercial laboratory is used that reports automatically to the State) and report all positive test results to the local health department immediately upon notification of those results. Fax PH1600 form to 615-741-3857. <https://www.tn.gov/content/dam/tn/health/documents/reportable-diseases/PH-1600.pdf>
- ☐ Accept 4. Record the individual's testing information in an office log that includes the date of testing, the date of the result notification, the result of the test, the source of specimen collection (nasopharyngeal, nasal, saliva, oropharyngeal), the method of specimen collection (health care provider collection, observed self-collection, self-collection), if the individual had known exposure to COVID-19, if the individual was symptomatic at the time of testing, date of onset of symptoms, the date of notification to Tennessee Department of Health (TDH), the date of notification to the local health department if the result was positive, and the date the individual was notified of test results.

AGREEMENT OF UNDERSTANDING (cont'd.)

In addition, the requesting organization:

- ☐ Accept 5. Shall not charge individuals, health insurance plans, or other third-party payers for the test or any testing supplies provided at no cost to the organization.
- ☐ Accept 6. Must report the number of tests conducted each week and the numbers of positive and negative results (aggregate, de-identified data) to COVID19.Testing@tn.gov.
- ☐ Accept 7. Must provide the individual with a written record of their test result and date of testing unless the patient has access to their results via an online portal.
- ☐ Accept 8. Shall assure that all persons participating in the COVID-19 testing program at this organization are made aware of their obligations under the terms of this agreement.
- ☐ Accept 9. Shall not refuse to provide testing to an eligible individual until notified by the State of Tennessee that the testing initiative has been suspended or discontinued.
- ☐ Accept 10. Acknowledges that negative results obtained through rapid antigen testing should be confirmed by molecular-based testing (PCR).

Additional conditions – the testing organization acknowledges that:

- ☐ Accept 11. TDH reserves the right to inspect testing supply inventory at will.
- ☐ Accept 12. TDH reserves the right to recall or redirect issued testing supplies as dictated by the department's outbreak response needs.
- ☐ Accept 13. The timing and amounts for distribution of these testing supplies will be at the sole discretion of TDH.

Medical Director (or Authorized Designee) Signature

Date

INTERNAL USE ONLY

Dr. Lisa Piercey, MD, MBA, FAAP
Commissioner, Tennessee Department of Health

Date

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

ORGANIZATIONS WITH MULTIPLE LOCATIONS

Name of Organization

FACILITY # 1

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

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Phone

Fax

E-mail

FACILITY # 2

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

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Phone

Fax

E-mail

FACILITY # 3

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

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Phone

Fax

E-mail

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

ORGANIZATIONS WITH MULTIPLE LOCATIONS (cont'd.)

Name of Organization

FACILITY # 4

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

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Phone

Fax

E-mail

FACILITY # 5

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

() -

Phone

Fax

E-mail

FACILITY # 6

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

() -

Phone

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